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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,012	11/26/2001	Peter M. von Dyck	713072.28	1623

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HUSCH & EPPENBERGER, LLC
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ST. LOUIS, MO 63105-3441

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,012

Applicant(s)

VON DYCK ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-69 is/are allowed.
- 6) ☒ Claim(s) 38 and 40-46 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 3/30/05 has been received and made of record. As requested claim 39 has been amended.
2. Claims 38-69 are pending.

Allowable Subject Matter

3. Claims 47-69 are allowed.
4. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 38, 40, 41, 42, 43, 45 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,350,255 ("the '255 patent") in view of U.S. Patent No. 4,867,748 ("Samuelson").

As regards claim 38, the '255 patent substantially discloses all features of the claim. As can be seen from claim 1, the '525 patent discloses a pad for use with a continent ostomy port, the pad comprising a body portion having an internal wall defining an aperture appropriately sized to place around a stoma, the body portion of the pad being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port, the pad being formed of a soft, flexible material to thereby cushion and protect the skin from contact with the ostomy port face plate.

The '255 patent fails to teach that the body portion of the pad has a stepped configuration on a distal surface thereof, the stepped configuration consisting of at least two distinct levels. However, as can be seen from Fig. 2 and as can be read from col. 3, line 27-col. 4, line 44, Samuelson discloses a dressing comprising a pad (4) having an aperture (11) for engaging a stoma or drain. Samuelson further discloses that the dressing is beveled having a reduced thickness around the edge of the aperture, thereby having a stepped configuration, in order to prevent sealing material from the pad from flowing out from under the pad, thereby reducing adherence of the pad (col. 1, lines 19-col. 2, lines 68).

In view of Samuelson, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the pad of the '255 patent with a stepped

configuration in order to prevent sealing material from the pad from flowing out from under the pad, thereby reducing adherence of the pad (col. 1, lines 19-col. 2, lines 68).

As to claims 40 and 41, claim 2 of the '255 patent recites that that pad is formed of open cell foam. Consequently, the examiner contends that the pad material is both **capable** of being disposed of and being facilely cleaned and reused.

As regards claims 42, the '255 patent is silent as to the pad being coated with a thin, liquid permeable skin to thereby trap wicked moisture within the pad. Samuelson, however, discloses at col. 3, lines 38-42 that "[t]he cover layer is preferably a film of water-tight (and hence water insoluble) material, e.g. a polyurethane, polyethylene, polyester or polyamide film, or a thin foam material of for instance one of the same materials." Thus, disclosing a thin water impermeable layer skin, which is **capable** of trapping wicked moisture within the pad and is used when connecting the dressing (pad) to other objects (col. 3, lines 42-45).

In view of Samuelson, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pad of the '255 patent with a thin water impermeable cover layer for use in connecting the dressing to other objects.

As regards claim 43, note the rejection of claims 38 and 42 above.

As regards claims 45 and 46, claim 2 of the '255 patent recites that that pad is formed of open cell foam. Consequently, the examiner contends that the pad material is both **capable** of being disposed of and being facilely cleaned and reused.

7. Claim 44 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of the '255 patent in view of

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Samuelson as applied to claim 43 above, and in further view of U.S. Patent No. 5,208,313 ("Krishnan").

As regards claim 44, the modified device of the '255 patent fails to teach that the liquid impermeable layer is air permeable. However, Krishnan discloses a waterproof, breathable polyurethane membrane that can be used as a coating on material in order prevent water or liquid from penetrating the coating through to the material and to allow the exchange of air through the coating.

In view of Krishnan, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coat the pad of the '255 patent with a waterproof, breathable polyurethane membrane that can be used as a coating on material in order prevent water or liquid from penetrating the coating through to the material and to allow the exchange of air through the coating.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 38, 40, 42, 43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson.

As regards claim 38, Samuelson substantially discloses all feature of the claim. More specifically, Samuelson discloses a pad **capable** of use with a continent ostomy port, the pad (4) comprising a body portion having an internal wall defining an aperture (11) appropriately sized to place around a stoma (col. 4, lines 26-35), the body portion of the pad **capable** of being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port. Samuelson further discloses that the dressing is beveled having a reduced thickness around the edge of the aperture, thereby having a stepped configuration, in order to prevent sealing material from the pad from flowing out from under the pad, thereby reducing adherence of the pad (col. 1, lines 19-col. 2, lines 68).

Samuelson fails to teach that the pad is formed of a soft, flexible material to thereby cushion and protect the skin from contact with the ostomy port face plate. However, given the environment in which the pad is used, it would have been *prima facie* obvious to one having ordinary skill in the art to construct the pad from a soft, flexible material to 1) allow the pad to be placed around the stoma, and 2) to minimize irritation to the stoma.

As regards claim 40, pad is formed of a material, which is readily disposable.

As regards claim 42, Samuelson, discloses at col. 3, lines 38-42 that "[t]he cover layer is preferably a film of water-tight (and hence water insoluble) material, e.g. a polyurethane, polyethylene, polyester or polyamide film, or a thin foam material of for instance one of the same materials." Thus, disclosing a thin water impermeable layer skin, which is **capable** of trapping wicked moisture within the pad.

As regards claim 43, note the rejection of claims 38 and 42 above.

As regards claim 45, note the rejection of claim 40 and 43 above.

12. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson in view of Krishnan.

As regards claim 44, Samuelson fails to teach that the liquid impermeable layer is air permeable. However, Krishnan discloses a waterproof, breathable polyurethane membrane that can be used as a coating on material in order prevent water or liquid from penetrating the coating through to the material and to allow the exchange of air through the coating.

In view of Krishnan, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coat the pad of the '255 patent with a waterproof, breathable polyurethane membrane that can be used as a coating on material in order prevent water or liquid from penetrating the coating through to the material and to allow the exchange of air through the coating.

13. Claims 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,219,023 ("Galindo").

As regards claim 38, Galindo substantially discloses applicants' presently claimed invention. More specifically, Galindo discloses a pad (constituted by cushion member 24) capable of use with a continent ostomy port. As can be seen from Figs. 2 and 3, the pad comprising a body portion having an internal wall defining an aperture (26) appropriately sized to place around a stoma (col. 3, lines 55-63). The body portion of the pad capable of being sized and shaped for placement against a user's skin beneath a face plate of an ostomy port, wherein the body portion of the pad has a stepped configuration on a distal surface thereof, the stepped configuration consisting of at least two distinct levels (constituted by the two different levels of the pad in Fig. 2).

Galindo fail to teach that the pad is formed of a soft, flexible material to thereby cushion and protect the skin from contact with the ostomy port face plate. However, given the environment in which the pad is used, it would have been *prima facie* obvious to one having ordinary skill in the art to construct the pad from a soft, flexible material to

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1) allow the pad to be placed around the stoma, and 2) to minimize irritation to the stoma.

As regards claim 41, Galindo discloses that the pad can be a sponge, which is capable of being facilely cleaned and reused.

14. Claim 42, 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galindo in view of Samuelson.

As regards claim 42, Galindo fails to teach that the distal surface of the pad is coated with a thin liquid permeable skin. Samuelson, however, discloses a pad capable of use with and continent ostomy port. More specifically, Samuelson discloses at col. 3, lines 38-42 that "[t]he cover layer is preferably a film of water-tight (and hence water insoluble) material, e.g. a polyurethane, polyethylene, polyester or polyamide film, or a thin foam material of for instance one of the same materials." Thus, disclosing a thin water impermeable layer skin, which is **capable** of trapping wicked moisture within the pad and is used when connecting the dressing (pad) to other objects (col. 3, lines 42-45).

In view of Samuelson, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the pad of the '255 patent with a thin water impermeable cover layer for use in connecting the dressing to other objects.


As regards claim 43, note the rejection of claims 38 and 42 above.

As regards claim 46, Galindo discloses that the pad can be a sponge, which is capable of being facilely cleaned and reused.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
July 9, 2005